Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women: a randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women

Design
A concealed, randomized, triple blind, controlled clinical trial with a parallel group design of 88 women, phase 3.

Settings and conduct
Sampling will be done in densely populated and socio-economically different centers of Malayer. Participants in the study will be assigned to two groups by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . The allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnant women with gestational age of 8-10 weeks and vitamin D levels below 30 ng/ml. Exclusion criteria: women with diabetes, thyroid and parathyroid disorders; history of macrosom neonate; body mass index above 30 kg/m2 before pregnancy; pre-pregnancy polycystic ovary syndrome and history of diabetes or gestational diabetes will be excluded from the study.

Intervention groups
The intervention group will receive 4 oral tablets of vitamin D 1000 units daily and the control group will receive placebo which is quite similar in appearance to the drug used in the intervention group.

Main outcome variables
Sleep quality; pregnancy symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N61**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **prospective**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date
2021-01-15, 1399/10/26

Registrant information
Name
Mojgan Mirghafourvand
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6969
Email address
mirghafourvandm@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-19, 1399/10/30

Expected recruitment end date
2021-05-20, 1400/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women: a randomized controlled clinical trial

Public title
The effect of vitamin D on sleep quality and pregnancy symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant people with a gestational age of 8 -10 weeks Vitamin D levels below 30 ng/ml
Exclusion criteria:
Women with diabetes Vitamin D levels above 30 ng/ml Women with thyroid and parathyroid disorders according to the self-report Women with a body mass index above 30 kg/2m before pregnancy Women with a history of macrosomic neonate Women with pre-pregnancy polycystic ovary syndrome, according to the self-report Women with a history of diabetes or gestational diabetes
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be assigned to two groups (one group receiving 4,000 units of oral vitamin D daily and one group receiving placebo with the same protocol) by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2020-12-14, 1399/09/24
Ethics committee reference number
IR.TBZMED.REC.1399.869

Health conditions studied

1

Description of health condition studied
Sleep Quality
ICD-10 code
G47.9
ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
Sleep quality score
Timepoint
Before the intervention and 26th week of pregnancy
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Pregnancy symptoms score
Timepoint
Before the intervention and 26th week of pregnancy
Method of measurement
Pregnancy Symptoms Questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
During intervention
Method of measurement
Side effects checklist

Intervention groups

1

Description
The intervention group will receive 4000 units of oral vitamin D daily produced by Dana Pharmaceutical Company, which is quite similar in appearance to the drug used in the placebo group. This intervention will last for 18 weeks.
Category
Prevention

2

Description
The control group will receive an oral placebo daily produced by Dana Pharmaceutical Company, which in terms of appearance is quite similar to the drug used in the intervention group. This study will last for 18 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Malayer city
Full name of responsible person
Zahra Mirzaee Azandaryani
Street address
Malayer city
City
Malayer
Province
Hamadan
Postal code
6578146769
Phone
+98 81 3231 2259
Email
z.mirzaee2019@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947979
Phone
+98 41 3479 6969
Email
iro@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Zahra Mirzaee Azandaryani
Position
MSc student of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947979
Phone
+98 41 3177 2048
Email
z.mirzaee2019@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mojgan Mirghafourvand

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing & Midwifery, South Shariati Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138947979

Phone
+98 41 3177 2048

Email
mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mojgan Mirghafourvand

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, South Shariati St,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138947979

Phone
+98 41 3177 2048

Email
mirghafourvandm@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participant data is confidential.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available